REMARKS

Claims 1-29, 31-35, 41-42 and 44-50 are pending and claims 23, 26, 29, 31, 33, 35, 41, 42 and 44 are withdrawn.

Applicants have amended claim 14 to improve its form and to more particularly point out the claimed invention. The amended claims are fully supported by the specification (e.g., Examples 2 and 3) and originally filed claim 14. Accordingly, no new matter has been introduced.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

DETAILED ACTION

Election/Restriction

1-2. Applicants acknowledge that claims 23, 26, 29, 31, 33, 35, 41, 42, and 44 are withdrawn.

Double Patenting Rejection

3-4. Claims 1-22, 24, 25, 27, 28, 32, 34, and 45-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-14 of copending application no. 11/127,438. Applicants respectfully request that the Examiner hold this provisional rejection in abeyance until allowable subject matter is identified in the instant application. Once allowable subject matter has been identified, Applicants will evaluate the filing of a terminal disclaimer or providing arguments in view of the claims pending at that time.

Claim Rejections Under 35 U.S.C. § 112

5. Claim 21 was rejected under 35 U.S.C. § 112 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

MPEP 2173.05(b) states:

> The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

Applicants respectfully remind the Examiner that according to the MPEP claim language that is acceptable if one of ordinary skill in the art would be able to understand what is claimed in light of the specification. Here the specification provides sufficient guidance to one of ordinary skill for interpreting the claims. The term "substantially reducing" as used in claim 21 is clearly used in the specification to describe the effect of intravenous administration of the anti-C5 antibody, but not aerosol administration (see page 23, lines 1-11, page 24, lines 6-14, and Figure 7). Specifically, Figure 7 shows that in a subject in which anti-C5 antibody BB5.1 was administered via aerosol the systemic complement activity was approximately 93% of the control. This is about a 7% reduction. In comparison, intravenous administration led to almost 80% reduction of the systemic complement activity (see page 25, lines 7-17). In fact, the specification specifically states that "aerosol administration did so without substantially reducing systemic C5 activity" (see page 25, lines 15-17). As required by the MPEP, in light of the specification, one of ordinary skill in the art would understand the claimed subject matter.

This standpoint is further consistent with the same MPEP section, which particularly listed the use of the word "substantially" as being definite if a skilled artisan would be reasonably apprised of the meaning of the term, especially in view of the guidelines set forth in the

specification. *See, In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). In *In re Mattison*, the court held that the limitation 'to substantially increase the efficiency of the compound as a copper extractant' was definite in view of the general guidelines contained in the specification. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). A similar result was also seen in *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988), where the Court held that the limitation 'which produces substantially equal E and H plane illumination patterns' was definite because one of ordinary skill in the art would know what was meant by 'substantially equal.' It is Applicants position, that in this case, the term substantially is being used consistent with the usage in *Mattison* and *Andrew Corp.* Accordingly, it is urged that claim 21 is definite and reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. § 103

6. Claims 1-10, 18, 22, 24, 25, 27, 28, 32, and 34 are rejected under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Drouin (J. Immunol. [2001] 166:2025-2032). The Examiner states that Drouin teaches that C5a receptors are increased on bronchial epithelial and smooth muscle cells in sepsis and in asthma and that septic primates and rats that are treated with anti-C5a antibodies have reduced pulmonary edema and lung injury. The Examiner argues that it would have been obvious to a person of ordinary skill in the art to treat subjects with asthma using an antibody that inhibits C5 or C5a based on the teachings of Drouin. Applicants respectfully disagree.

The Examiner refers to page 2029, column 2 of Drouin to support the position that that C5aR is upregulated in asthma. At page 2029, Drouin states: "[m]oreover, we have established that both receptors are up-regulated in two distinct models of lung inflammation: endotoxemia and OVA-induced asthma." It is Applicant's position, that as a matter of law, this isolated statement must properly be interpreted in view of the teachings of the reference taken as a whole. The data provided in this article clearly show that C3aR was upregulated in both the endotoxemia (LPS) model and the OVA-challenged mouse model but C5aR was upregulated ***only*** in the LPS model (see final paragraph on page 2028 continuing onto page 2029). Therefore, when taken in context, this sentence means that the authors used two different models and saw upregulation of two

different receptors, with one receptor (C3aR) being upregulated in both models, but the other (C5aR) being upregulated in only one model.

The Examiner also argues that the Abstract states that C5aR is relevant to asthma, but in fact, the Abstract, merely states that bronchial epithelial and smooth muscle cells participate in sepsis and asthma. Specifically, as the Examiner points out, the Abstract states that both C3aR and C5aR have a role during lung inflammation. However, the publication teaches two models of inflammation and shows a role of the C5aR in only one of these two models, i.e., it shows a role in the sepsis model but not in the asthma model.

Drouin states that C5aR expression is increased in lungs when an LPS model of endotoxemia was used (see final paragraph on page 2028 continuing onto page 2029). However, by contrast, when an OVA model of asthma was used, C5aR expression did not increase. This is stated throughout the publication (in the *Abstract* which states, "C5aR expression also increased significantly on bronchial epithelial cells in mice treated with LPS, but was not elevated in either cell type in the OVA-challenged mice"; in the *Results* as set forth in the right-hand column, lines 5-7, on page 2029 which state, "In contrast to mice treated with LPS, C3aR and C5aR expression in OVA-challenged lungs did not change on bronchial (Fig. 6, bottom) and alveolar epithelial cells; and in the *Discussion* on page 2031, left-hand column, lines 6-9 of the first full paragraph, which state, "In contrast to mice treated with LPS, C3aR and C5aR expression did not change on bronchial and alveolar epithelial cells from OVA-challenged lungs."). The data on pages 2028-2029 show that, although C3aR may be relevant for both sepsis and asthma, C5aR appears to be relevant only for sepsis, not asthma. C5aR expression in OVA-challenged lungs did not change on bronchial and alveolar epithelial cells and no statement was made as to whether C5aR changed expression on the smooth muscle cells in this model. It is Applicant's position that this lack of evidence of a change in C5aR expression in lung cells in the asthma model teaches away from the instant claims. If Applicants have overlooked any data in the Drouin publication which show that C5aR expression is increased in the lungs in the OVA model, it is requested that the Examiner point this data out with specificity.

The Examiner also states that "Drouin teaches that septic primates and rats that are treated with anti-C5a antibodies have reduced pulmonary edema and lung injury" pointing to page 2031, first column. This refers only to sepsis and thus the endotoxemia model. One of ordinary skill in the art would not find this relevant to the asthma model.

In view of the Abstract not reciting that C5aR is relevant to asthma and the actual data which also does not show this, the Examiner's reliance on the sentence on page 2029, column 2, is misplaced as the publication clearly teaches a lack of C5aR upregulation in the OVA model. Therefore, Drouin teaches away from inhibiting C5 or C5a.

Thus, Drouin does not teach or suggest all elements of claims 1-10, 18, 22, 24, 25, 27, 28, 32, and 34, and it would not have been obvious to one of skill in the art how to make up for these deficiencies, especially since Drouin teaches away from the instant claims. Accordingly, the claims are non-obvious over the cited prior art, and reconsideration and withdrawal of this rejection are respectfully requested.

7. Claims 11-13, 15 and 16 are rejected under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Drouin (J. Immunol. [2001] 166:2025-2032) and further in view of Fitch et al. The Examiner states that Drouin does not teach the treatment of human subjects and the h5G1.1 antibody, but that Fitch et al. does. The Examiner argues that is would have been obvious to a person of ordinary skill in the art to use the h5G1.1 antibody to treat airway inflammation in a human target, such as one with asthma. Applicants respectfully traverse.

The teachings of Drouin are discussed *supra*. The deficiencies of Drouin are not provided by Fitch et al. Neither reference teaches that C5aR is relevant to asthma. Thus, the references taken in combination do not teach or suggest all elements of claims 11-13, 15 and 16. Accordingly, the claims are non-obvious over the cited prior art, and reconsideration and withdrawal of this rejection are respectfully requested.

8. Claims 17 and 45-48 are rejected under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Drouin (J. Immunol. [2001] 166:2025-2032) and further in view of US Patent 4,228,795 ('795 patent) to Babington. The Examiner states that Drouin does not teach a disperser, but that the '795 patent teaches a nebulizer. The Examiner argues that is would have been obvious to a person of ordinary skill in the art to use the nebulizer taught by the '795 patent to administer the anti-C5a antibodies taught by Drouin. Applicants respectfully traverse.

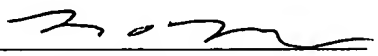
Drouin has been discussed supra, and the '795 patent teaches a nebulizer. Neither reference teaches that C5aR is relevant to asthma. Thus, Drouin does not teach or suggest all elements of claims 11-13, 15 and 16, and the '795 patent does not make up for these deficiencies. Accordingly, the claims are non-obvious over the cited prior art, and reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Please charge any fees or credit any overpayments to our Deposit Account No. 18-1945 from which the undersigned is authorized to draw, under order no. ALXN-P01-102.

Dated: January 7, 2008

Respectfully submitted,

By 

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